

REMARKS

Claims 1-4 and 6-12 were examined. Independent claims 1, 6 and 10 are amended. Dependent claim 3 is amended. Claim 5 is cancelled. Therefore, claims 1-4 and 6-12 are presented for examination.

The Patent Office rejects claims 1-4 and 6-12 under 35 U.S.C. § 112. The Patent office rejects claims 1-4, 6-12 under the judicially created doctrine of obviousness-type double patenting. The Patent Office rejects claims 1-4 and 6-12 under 35 U.S.C. § 103(a). Reconsideration of the rejected claims is requested in view of the following remarks.

35 U.S.C. §112 Rejection of Claim 1-4, 6-12

Claim 1-4, 6-12 were rejected by The Patent Office under 35 U.S.C. §112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter. The rejection has been obviated by the amendment to claims 1,6 and 10 by removing "comprise a portion of a periodic amount of dietary fiber" and adding " comprises at least 10 percent of the daily amount of dietary fiber." This amendment is supported in the specification by paragraphs [0006], [0008], [0021], [0028], [0029] and [0030]. As follows, dependent claim 3 has been amended to accommodate the change in independent claim 1 to read "about 4 to 33 percent." Accordingly, Applicant respectfully requests the withdrawal of the rejection.

In addition, the Patent Office indicates that the Independent claims 1,6 and 10 are open comprising claims. The Applicant has amended Independent claims 1,6 and 10 by replacing "a dietary acceptable amount of a first soluble fiber comprising inulin" with "a dietary acceptable amount of a first soluble fiber of inulin." The Applicant requests withdrawal of the objection.

Double Patenting

Claim 1-4, 6-12 were rejected by the Patent office under the doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of Forusz et al. (Forusz, U.S. Patent No. 6,436,446). Applicant would like to call attention to claims 1-9 of Forusz that are directed toward a calcium solution used for reducing the risk of bone density loss. Each claim 1-9 of Forusz includes a calcium component for reducing the risk of bone density loss. The present invention is directed toward a fiber solution of low viscosity and high fiber content. The present invention is directed toward a dietary fiber formulation that may be used to promote intestinal health in a subject. The claims 1-4, 6-12 are not directed toward a calcium supplement and calcium is not required for the preparation of these solutions. Therefore, Applicant requests withdraw of the double-patenting rejection by the Patent Office.

A. 35 U.S.C. §103(e) Rejection of Claim 1-4, 6-12

The Patent Office rejects claims 1-4, 6-12 under 35 U.S.C. § 103(e) as being unpatentable over U.S. Patent No. 6,436,446 issued to Forusz et al. (Forusz). As presented previously, Forusz discloses a formulation that includes calcium to prevent bone loss in a subject. The present invention discloses a dietary source of a translucent high-fiber formulation. These formulations are not directed toward a calcium supplement. The formulations of Forusz and the present invention do not include the same instant ingredients. The principal ingredients of one are not the principal ingredients of the other. Forusz formulations contain the principal ingredient of calcium, a mineral definitively directed in Forusz toward the prevention of bone loss. Forusz fails to disclose the limitations of Claims 1, 6 and 10 "a dietary acceptable amount of a first soluble fiber of inulin" "comprises at least 10 percent of the daily amount of dietary fiber." Therefore, the Applicant requests withdraw of the rejection.

A. 35 U.S.C. §103(a) Rejection of Claim 1-4, 6-12

The Patent Office rejects claims 1-3, 6-12 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,248,390 issued to Stillman et al. (Stillman) or U.S.

Patent No. 6,245,326 issued to Topping et al. (Topping) in view of E.P. No. 0756, 828 issued to Green et al. (Green) or in view of, French application No. 2778849 of Christine (Christine).

A prima facie case of obviousness requires that: [1] the cited references, alone or in combination, disclose each and every claim limitation; [2] there is some suggestion or motivation, either in the cited references or in the general knowledge in the art, to modify or combine the reference teachings; and [3] there is a reasonable expectation of success in achieving the claimed invention. [MPEP 2142; *In re Vaeck*, 947 F.2d 488, (Fed. Cir. 1991).]. Applicants respectfully submit that the Patent Office failed to establish a prima facie case of obviousness. Specifically, the cited references, alone or in combination, fail to disclose the elements of

" a dietary acceptable amount of a first soluble fiber of inulin; and
a dietary acceptable amount of a second soluble fiber selected from the group consisting of at least one of maltodextrin, polydextrose and acacia gum wherein the composition is a translucent beverage having a viscosity on the order of 1.4 centipoise or less at a pH less than six and wherein a collective amount of the amount of the first soluble fiber and the second soluble fiber comprises at least 10 percent of the daily amount of dietary fiber."

There also is no motivation to combine the reference teachings. Further, the skilled artisan reading the cited references would have had no reasonable expectation of achieving the claimed invention.

According to the Patent Office, 'Stillman discloses a beverage containing water and the soluble fibers, inulin and maltodextrin, which is optically clear and which contains predetermined amounts of from 0.1% to 10% fiber (col. 4, lines 54-60 and col. 15, lines 60-70)'. Stillman describes a beverage that contains inulin and guar gum (col. 15, lines 60-66). Also, Stillman discloses a beverage containing one or more fiber sources to be used as bulking agents to maintain the health of patients. The "fiber-water" as described in the abstract of Stillman is principally used for proper hydration and secondly used as a source of fiber. "Fiber-water is safe water fiber enriched intending to be a replacement and/or adjunct to other water to ensure proper hydration while at the same time provide significant soluble fiber." Stillman fails to address the importance of the balance of the fibers as in claim 1

whereby the overall viscosity of the translucent composition is specified. Stillman fails to describe the limitation disclosed in Claim 1 in which inulin is the first fiber. The fiber concentrations in the beverages in Stillman are decided (between 0.1% and 10% according to claim 1) but the final viscosity of the beverages is not. Claim 1 describes a combination of fibers that is “at least 10 percent of the daily amount of dietary fiber.” This is not the case in Stillman. In addition, there is no pH limitation in the compositions of Stillman since the supplements in Stillman appear to be in a water-soluble dry form.

According to the Patent Office, Topping discloses a composition containing, inulin and maltodextrin, which can be a beverage (col. 2, lines 53-59, col.4, lines 7-9 and lines 64-68). Applicant admits that the invention of Topping may include inulin and /or maltodextrin but as directed in col.4 lines 7-9 of Topping, inulin is used as a fatty acid promoter (an FACBC, fatty acid covalently bound to a carrier) while bound to a SCFA (short chain fatty acid) not as a principal source of fiber as in claim 1 of the Application. As indicated, col. 4 lines 64-68 of Topping disclose one of the instant ingredients may be maltodextrin but the maltodextrin of Topping is a processing aid in the composition not a source of fiber.

According to the Patent Office, Topping discloses a composition containing psyllium, inulin and maltodextrin and other soluble gums such as pectin and guar gum. Topping fails to disclose a composition of a translucent beverage having a viscosity on the order of 1.4 centipoise or less. Topping fails to disclose a pH. less than six. In Topping, the compositions are directed toward cholesterol reduction and faecal bulk promotion. The ingredients inulin and maltodextrin of Topping are directed toward an FACBC and a processing aid respectively not a low viscosity high fiber composition as in the Application. Topping fails to disclose “wherein a collective amount of the amount of the first soluble fiber and the second soluble fiber comprises at least 10 percent of the daily amount of dietary fiber.”

According to the Patent Office, Green discloses a soluble fiber, inulin and a second soluble fiber in amounts from 8-40% as in a dry mix (col. 3, lines 12-30). The composition can be mixed with water in amounts of 2 grams. Independent claim 1 discloses a fiber composition that “is a translucent beverage having a viscosity on the order of 1.4 centipoise or less at a pH less than six.” Green fails to address maintenance of low viscosity on the order of 1.4 centipoise or less and Green fails to address the limitation of a specific pH of

less than six. The limited pH range is such that "inulin and the other soluble fiber(s) such as maltodextrin are stable in solution and the acidic nature controls bacteria growth ([0010] of the specification)." In addition, Green fails to disclose "wherein a collective amount of the amount of the first soluble fiber and the second soluble fiber comprises at least 10 percent of the daily amount of dietary fiber."

The reference of Green fails to cure the deficiencies of Stillman or Topping. Green is cited for describing a dried mixture of fibers and oligosaccharides that may be added to water. Col. 4 line 40-41 of Green discloses the pH of a liquid composition preferably between 4 and 8. The current invention may not exceed the pH of around six. As a preliminary matter, Green fails to disclose that its second fiber that is at least one of maltodextrin, polydextrin, and acacia gum. Green fails to disclose a translucent beverage having a viscosity of 1.4 centipoise or less.

The reference of Christine (French application No. 2778849 of Christine.) referred to in a previous office action and mentioned on page 6 paragraph 4 of this office action discloses use of 5% arabinoxylanes. Assuming for doctrine of equivalent purposes that arabinoxylanes and inulin are equivalent components,¹ it does not necessarily follow that because Christine describes a composition having 5% arabinoxylanes, the composition has a viscosity of 1.4 centipoise or less. The reference of Christine fails to cure the deficiencies of Stillman and Green, and Topping. Christine fails to disclose a composition of a translucent beverage having a viscosity on the order of 1.4 centipoise or less. Christine fails to disclose a pH. less than six to increase stability of the fibers in solution (e.g.inulin). Christine fails to disclose "wherein a collective amount of the amount of the first soluble fiber and the second soluble fiber comprises at least 10 percent of the daily amount of dietary fiber."

Claim 1 is prima facie not obvious over the cited references, because the references fail to describe a composition of " and wherein a collective amount of the amount of the first soluble fiber and the second soluble fiber comprises at least 10 percent of the daily amount of dietary fiber." There is similarly no motivation from the cited references to combine "a

¹ *Christine* refers to arabinoxylanes that, according to Applicants' representative's research is a primary component of wheat and rice bran. Inulin is a fructose polymer isolated principally from Chicory root.

collective amount of the amount of the first soluble fiber and the second soluble fiber comprises at least 10 percent of the daily amount of dietary fiber” at a viscosity of 1.4 or less.

For the above reasons, independent claim 1 is not obvious over the cited references. Claims 2-4 depend from claim 1 and therefore contain all the limitations of that claim and include additional limitations. Therefore, claims 2-4 are not obvious over the cited references.

Independent claim 6 relates to a method including administering "a translucent beverage composition comprising a first soluble fiber of inulin and a second soluble fiber." The composition has a viscosity on the order of 1.4 centipoise or less at a pH less than six. The composition would not necessarily be a beverage but could be a solid or a powder used to form a beverage in a method of administering a beverage comprising two soluble fiber components. If the composition is a powder, the powder would be mixed with a liquid and the pH would be adjusted (if required) to less than six in order to stabilize the fibers in solution such as inulin.

Claim 6 is not prima facie obvious because the Patent Office fails to describe a solubilized dual fiber translucent composition with a limited viscosity in the form of a beverage for human consumption and “wherein a collective amount of the amount of the first soluble fiber and the second soluble fiber comprises at least 10 percent of the daily amount of dietary fiber”. As noted above, none of the references recite administering a beverage of the claimed viscosity. Further, there is no motivation from the various combination of references to administer a beverage of the claimed viscosity where inulin is a required first soluble fiber and the second soluble fibers are “at least one of maltodextrin, polydextrose and acacia gum.”

For the above stated reasons, independent claim 6 is not obvious. Claims 7-9 depend from claim 6 and contain all the limitations of that claim and additional limitations. Therefore, claims 7-9 are not obvious over the cited references.

Independent claim 10 relates to a method including administering "a translucent beverage composition comprising a first soluble fiber of inulin and a second soluble selected from the group consisting of at least one of maltodextrin, polydextrose and acacia gum

wherein the composition has a viscosity on the order of 1.4 centipoises or less at a pH of less than six and “wherein a collective amount of the amount of the first soluble fiber and the second soluble fiber comprises at least 10 percent of the daily amount of dietary fiber” The composition has a viscosity on the order of 1.4 centipoise or less at a pH less than six. The composition would not necessarily be a beverage but could be a solid or a powder used to form a beverage in a method of administering a beverage comprising two soluble fiber components where the first soluble fiber is inulin.

Claim 10 is not prima facie obvious because the Patent Office fails to describe a solubilized single strength translucent beverage for human consumption of dual fibers with a limited components, limited viscosity and limited pH. As noted above, none of the references recite administering a beverage of dual fibers of the claimed viscosity comprising “at least 10 percent of the daily amount of dietary fiber.” Further, there is no motivation from the various combination of references to administer a beverage of the claimed percent and viscosity.

For the above stated reasons, independent claim 10 is not obvious. Claims 11-12 depend from claim 10 and contain all the limitations of that claim and additional limitations. Therefore, claims 11-12 are not obvious over the cited references.

Conclusion

Applicants respectfully submit that the Action fails to submit a case for Double Patenting. Accordingly, Applicant respectfully requests the withdrawal of the Double Patenting rejection. Independent claims 1, 6 and 10 and dependent claim 3 have been amended. Please enter these amendments. Applicants respectfully submit that the Action fails to present a prima facie case of obviousness for any pending claim. Accordingly, Applicant respectfully requests the withdrawal of the rejection. As the pending rejections of claims were under 35 U.S.C. § 112 and 35 U.S.C. § 103, Applicant submits that the pending claims are now in condition for allowance.

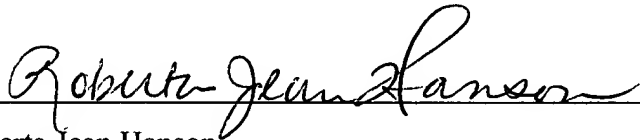
Invitation for a Telephone Interview

The Patent Office is requested to call the undersigned at (303) 740-1980 if there remains any issue with allowance of the case.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Date: February 26, 2004



Roberta Jean Hanson
Reg. No. 51,774

12400 Wilshire Boulevard
7th Floor
Los Angeles, California 90025-1026
(303) 740-1980